

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. ____

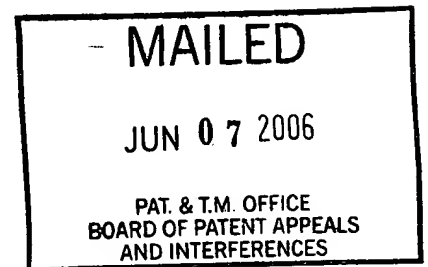
UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte THIERRY BOON-FALLEUR, PIERRE VAN DER BRUGGEN,
BENOIT VAN DEN EYNDE, ALINE VAN PEL, ETIENE DE PLAEN,
CHRISTOPHE LURQUIN, PATRICK CHOMEZ and CATIA TRAVERSARI

Appeal No. 2006-0956
Application No. 08/819,669¹

ON BRIEF



Before GRON, LANE and GRIMES, Administrative Patent Judges.

GRON, Administrative Patent Judge.

DECISION ON APPEAL UNDER 35 U.S.C. § 134

¹ Application for patent filed March 17, 1997. According to applicant, this application is a divisional of Application 08/142,368, filed May 2, 1994, now U.S. Patent 5,925,729, issued July 20, 1999; which is a continuation-in-part of Application 07/807,043, filed December 12, 1991, now U.S. Patent 5,342,774, issued August 30, 1994; which is a continuation-in-part of Application 07/764,365, filed September 23, 1991, abandoned; which is a continuation-in-part of Application 07/728,838, filed July 9, 1991, abandoned; which is a continuation-in-part of Application 07/705,702, filed May 23, 1991, abandoned.

1

Introduction

This is an appeal under 35 U.S.C. § 134 from an examiner's final rejections of Claims 183-191, all claims pending in Application 08/819,669, filed March 17, 1997. All pending claims stand finally rejected under 35 U.S.C. § 112, first paragraph, as supported by a specification which, as filed, would not have provided an adequate written description of the full scope of the subject matter claimed, and/or would not have enabled persons skilled in the art to make and use the full scope of the subject matter claimed without undue experimentation.

6

11

A. Grouping of claims

According to appellant's Brief on Appeal (BA), Claims 183-191 do not stand or fall together (BA 5). Appellant grouped Claims 183, 185, 186, 188, 189 and 191 together and grouped Claims 184, 187 and 190 separately (BA 5). The Examiner's Answer (EA) acknowledges that dependent Claims 184, 187, and 190 further limit the tumor rejection antigen precursors of Claims 183, 185, 186, 188, 189 and 191 to ones comprising "the amino acid sequence set forth in SEQ ID NO: 26, a tumor rejection antigen associated with MAGE-1" (EA 3). In his Examiner's Answer, the examiner first established a third claim grouping of Claims 189-191 which depend respectively from composition Claims 186-188 and further specify

16

21

1 that those compositions are "in the form of a vaccine" (EA 3).
Appellant objects that the examiner's belated grouping of
Claims 189-191 exceeded his authority and asks for our commentary
(Reply Brief (RB), p. 2).

6 We may review any question relating to matters affecting the
merits of twice rejected claims. 35 U.S.C. § 134; 37 CFR
§ 1.191(c) (Dec. 22, 2003). Here, however, the issue of whether the
examiner exceeded his authority in newly regrouping appellant's
twice rejected claims in the Examiner's Answer is moot. First,
appellant has agreed to the examiner's belated separate grouping of
11 Claims 189-191 (RB 2). Second, while composition Claims 189-191
further limit (35 U.S.C. § 112, fourth paragraph) the form of the
compositions of Claims 186-188, the generic compositions of
Claims 186-188 encompass the compositions of dependent
Claims 189-191. Third, we may select any one claim from each of
16 appellant's original groupings of claims and decide the appeal as
to the grounds of rejection for each grouping based on the claim
selected. 37 CFR § 1.192(c)(7). Thus, even presuming appellant's
objections are warranted, we may elect to decide the appealed
rejections under 35 U.S.C. § 112, first paragraph, of Claims 183,
21 185, 186, 188, 189 and 191 as a group based on the examiner's
rejection of Claim 189 or 191, and the appealed rejections under

1 35 U.S.C. § 112, first paragraph, of Claims 184, 187 and 190 as a
group based on the examiner's rejection of Claim 190.

B. Rejected claims

- 6 183. An isolated, MAGE tumor rejection antigen precursor protein, wherein said protein is encoded by a nucleic acid molecule, the complementary sequence of which hybridizes to SEQ ID NO: 8 at 0.1xSSC, 0.1% SDS, wherein said tumor rejection antigen precursor is obtainable from melanoma cells.
- 11 184. The isolated tumor rejection antigen precursor protein of claim 183, the amino acid sequence of which comprises the amino acid sequence set forth in SEQ ID NO: 26.
- 16 185. The isolated tumor rejection antigen precursor protein of claim 183, wherein said protein is a human protein.
- 21 186. Composition comprising the isolated tumor rejection antigen precursor protein of claim 183, and a pharmaceutically appropriate ingredient.
- 26 187. Composition comprising the isolated tumor rejection antigen precursor protein of claim 184, and a pharmaceutically appropriate ingredient.
- 31 188. Composition comprising the isolated tumor rejection antigen precursor protein of claim 185, and a pharmaceutically appropriate ingredient.
189. The composition of claim 186, in the form of a vaccine.
190. The composition of claim 187, in the form of a vaccine.
191. The composition of claim 188, in the form of a vaccine.

36 C. Examiner's rejections

The examiner twice rejected appellant's Claims 183-191 under 35 U.S.C. § 112, first paragraph, as not supported by a

1 specification which, as filed, adequately describes, and/or would
have enabled persons skilled in the art to make and use, the full
scope of the invention claimed. Based on three groupings of
claims, each defining appellant's invention with a different degree
of intricacy, the examiner argues that the supporting specification
6 would not have adequately described and/or enabled the full scope
of the invention of each group of claims for one or more of the
following three deficiencies.

First, the Examiner's Answer for the first time interprets
Claims 189-191 as being directed to compositions which are not just
11 vaccines, but vaccines defined on page 309 of the Illustrated
Dictionary of Immunology, Cruse and Lewis, CRC Press, Boca Raton,
FL, 1994, as follows (EA 4):

16 Vaccine: Live attenuated or killed organisms or parts or
products from them which contain antigens that can stimulate a
specific immune response consisting of protective antibodies
and T cell immunity. A vaccine should stimulate a sufficient
number of memory T and B lymphocytes to yield effector T cells
and antibody-producing B cells from memory cells. It should
21 also be able to stimulate high titers of neutralizing
antibodies. Invention [sic, injection?] of a vaccine into a
nonimmune subject induces active immunity against the modified
pathogens.

Interpreting the compositions of appellant's Claims 189-191 as
26 dictionary-defined vaccines, the examiner relied upon art of record
to support his view that appellant's specification would not have

1 adequately described, or enabled one skilled in the art to make and
use, the full scope of the dictionary-defined vaccines to which
appellant's claims are said to be drawn.

Second, the examiner argues that the MAGE tumor rejection
antigen precursors (hereafter MAGE TRAPS) of Claims 183, 185, 186,
6 188, 189 and 191 are not adequately described and/or would not have
been enabled by appellant's specification. Appellant's claims
define MAGE TRAPS solely by reference to melanoma cells from which
they were obtained and the polynucleotide sequence SEQ ID NO: 8 to
which polynucleotide sequences complementary to polynucleotides
11 encoding the claimed MAGE TRAPS will hybridize at 0.1xSSC, 0.1 %
SDS (AB 25, Claim 183). We understand the examiner's position to
be that persons skilled in the art would not have believed from
appellant's specification that the inventors thereof had possession
of the full scope of the inventions appellant claims, and/or that
16 persons skilled in the art would have been able to make and use the
same without undue experimentation. Appellant's specification
teaches that cytotoxic T lymphocytes (CTLs) target TRA/MHC
complexes, i.e., tumor rejection antigens/associated major
histocompatibility complex molecules. According to the examiner,
21 the supporting specification does not establish a correlation
between the full scope of claimed MAGE TRAPS from which MAGE TRAs

1 that form TRA/MHC complexes can be derived and the capacity for
sequences complementary to polynucleotide sequences which encode
the full scope of MAGE TRAPs encompassed by appellant's claims to
hybridize to SEQ ID NO: 8 at 0.1xSSC, 0.1 % SDS (EA 6, first two
para.; EA 10, para. 4-6; EA 11; EA 12, second para.; EA 15, third
6 full para.; EA 17, para. 4-5; EA 18, first para.; EA 19, first two
para.; EA 22, para. 3-4; EA 24, last para.; EA 25, para. 3-5; and
EA 26, para. 2-4).

Third, the examiner argues that appellant's specification does
not establish a correlation between amino acid sequence SEQ ID
11 NO: 26 in appellant's Claims 184, 187 and 190 and the full scope of
claimed MAGE TRAPs from which MAGE TRAs that form target TRA/MHC
complexes can be derived. Having established no nexus between
either hybridization to polynucleotide sequence SEQ ID NO: 8 or
amino acid sequence SEQ ID NO: 26 and the MHC complexing ability
16 of MAGE TRAs derived from the full scope of MAGE TRAPs claimed,
appellant's specification does not provide an adequate written
description of, and/or would not have enabled persons skilled in
the art to make and use, the full scope of MAGE TRAPs appellant's
claim for any functional utility the specification suggests.

Discussion

A. Claim interpretation

The examiner concluded that Claims 189-191 are drawn to conventional, dictionary-defined vaccines. The examiner defined all vaccines to which dependent Claims 189-191 are directed, and all vaccines encompassed by composition Claims 186-188 upon which Claims 189-191 respectively depend, in accordance with a dictionary definition of vaccine found on page 309 of the Illustrated Dictionary of Immunology, Cruse and Lewis, CRC Press, Boca Raton, FL, 1994 (EA 4). Using that definition of the term vaccine as the foundation for further action, the examiner presented publications and arguments in support of the view that appellant's specification does not establish that persons skilled in the art reasonably would have understood that applicant possessed all the MAGE TRAPs encompassed by appellant's Claims 183-185 or show that persons skilled in the art would have been able to successfully determine which of the MAGE TRAPs encompassed by Claims 183-185 would be useful in conventional, dictionary-defined vaccines without undue experimentation. The examiner erred in defining the terms of appellant's claims, interpreting the scope and content of the invention claimed, and setting the foundation for his rejections.

1 The examiner concluded that the compositions to which
Claims 186-191 are drawn encompass the vaccines defined on page 309
of the Illustrated Dictionary of Immunology, supra. However, it
does not appear that the examiner considered either the language of
the claims or the teachings in the specification relating to that
6 claim language. Claims 189-191 are directed to a MAGE TRAP
"composition . . . in the form of a vaccine" (BA 25). The use of
the phrase "in the form of a vaccine" in Claims 189-191 makes it
unclear whether composition Claims 186-191 necessarily are limited
to MAGE TRAP compositions which induce immunity in a nonimmune
11 subject or there is a minimum degree or extent to which the
compositions must stimulate an immune response consisting of
protective antibodies and T cell immunity. In none of the
examiner's expositions on the meaning of the term "vaccine" and the
patentability of claimed compositions comprising MAGE TRAPS do we
16 find any effort to interpret the meaning of the phrase "composition
. . . in the form of a vaccine" or to search the supporting
specification for reasons why the inventors used that particular
phrase. Rather, the examiner focuses entirely on extrinsic
evidence for one contemporary definition of the term "vaccine".
21 Moreover, we find in the examiner's answer and multiple supplements

1 thereto little or no effort to interpret the scope and content of
the invention claimed in light of appellant's disclosure.

Most recently, the Federal Circuit reemphasized how important
it is to begin the task of claim interpretation by considering the
intrinsic evidence, i.e., the claims, the specification, and the
6 prosecution history. Phillips v. AWH Corp., 415 F.3d 1303,
1316-1320, 75 USPQ2d 1321, 1327-1331, (Fed. Cir. 2005) (en banc).
Extrinsic evidence, such as dictionary definitions of terms, should
be considered after considering the intrinsic evidence. See
Vitronics Corp. V. Conceptronic, Inc., 90 F.3d 1576, 1582-1583,
11 39 USPQ2d 1573, 1576-77 (Fed. Cir. 1996):

It is well-settled that, in interpreting . . . [a] claim,
we] should look first to the intrinsic evidence of record,
i.e., . . . the claims, the specification and . . . the
prosecution history. See Markman[v. Westview Instruments,
16 Inc.], 52 F.3d [967,] . . . 979, 34 USPQ2d [1321,] . . . 1329
[(Fed. Cir. 1995)(in banc) aff'd 517 U.S. 370 (1996)]. Such
intrinsic evidence is the most significant source of the
legally operative meaning of disputed claim language.

21 First, we look to the words of the claims themselves
. . . to define the scope of the . . . invention. . . .
Although words in a claim are generally given their ordinary
and customary meaning, a patentee may choose to be his own
lexicographer and use terms in a manner other than their
26 ordinary meaning, as long as the special definition of the
term is clearly stated in the patent specification or file
history. . . .

31 Thus, second, it is always necessary to review the
specification to determine whether the inventor has used any
terms in a manner inconsistent with their ordinary meaning.

1 The specification acts as a dictionary when it expressly
defines terms used in the claims or when it defines terms by
implication. Markman, 52 F.3d at 979, 34 USPQ2d at 1330. As
we have repeatedly stated, "[c]laims must be read in view of
the specification, of which they are a part." Id. At 979,
6 34 USPQ2d at 1329. The specification contains a written
description of the invention which must be clear and complete
enough to enable those of ordinary skill in the art to
make and use it. Thus, the specification is always highly
relevant to the claim construction analysis. Usually, it is
11 dispositive; it is the single best guide to the meaning of a
disputed term.

Third, the court may also consider the prosecution
history

16 In most situations, an analysis of the intrinsic evidence
alone will resolve any ambiguity in a disputed claim term.
In such circumstances, it is improper to rely on extrinsic
evidence. See, e.g., Pall Corp. V. Micron Separations, Inc.,
21 66 F.3d 1211, 1216, 36 USPQ2d 1225, 1228 (Fed. Cir. 1995)
("In construing the claims we look to the language of the
claims, the specification, and the prosecution history.
Extrinsic evidence may also be considered, if needed to
assist in determining the meaning or scope of technical
26 terms in the claims.")

Liberally quoting from the opinions in Vitronics and Markman,
the Federal Circuit added, Phillips v. AWH Corp., 415 F.3d
at 1316-1317, 75 USPQ2d at 1327:

31 The Patent and Trademark Office ("PTO") determines the
scope of the claims in patent applications not solely on the
basis of the claim language, but upon giving claims their
broadest reasonable construction "in light of the
specification as it would be interpreted by one of ordinary
36 skill in the art." In re Am. Acad. Of Sci. Tech. Ctr.,
367 F.3d 1359, 1364 [70 USPQ2d 1827] (Fed. Cir. 2004). Indeed,
the rules of the PTO require that application claims must
"conform to the invention as set forth in the remainder of the
specification and the terms and phrases used in the claims

1 must find clear support or antecedent basis in the description
so that the meaning of the terms in the claims may be
ascertainable by reference to the description." 37 CFR
\$ 1.75(d)(1). It is therefore entirely appropriate for a
court, when conducting claim construction, to rely heavily
6 on the written description for guidance as to the meaning
of the claims.

In particular, the Phillips court criticized the significance
of dictionaries and treatises as a primary means for defining claim
terminology. Phillips v. AWH Corp., 415 F.3d at 1317-1318,

11 75 USPQ2d at 1330, said:

[W]hile extrinsic evidence "can shed useful light on the
relevant art," we have explained that it is "less significant
than the intrinsic record in determining 'the legally
operative meaning of claim language.'" C.R. Bard, Inc. v.
16 U.S. Surgical Corp., 388 F.3d 858, 862 [73 USPQ2d 1011]
(Fed. Cir. 2004), quoting Vanderlande Indus. Nederland BV v.
Int'l Trade Comm'n, 366 F.3d 1311, 1318 [70 USPQ2d 1696]
(Fed. Cir. 2004)

21 Within the class of extrinsic evidence, the court has
observed that dictionaries and treatises can be useful in
claim construction. . . . Because dictionaries, and especially
technical dictionaries, endeavor to collect the accepted
meanings of terms used in various fields of science and
26 technology, those resources have been properly recognized as
among the many tools that can assist the court in determining
the meaning of particular terminology to those of skill in the
art of the invention.

31 Phillips v. AWH Corp., 415 F.3d at 1320, 75 USPQ2d at 1332,
expressed concern that previously adopted methods for claim
interpretation have "placed too much reliance on extrinsic sources
such as dictionaries, treatises, and encyclopedias and too little

1 on intrinsic sources, in particular the specification and
prosecution history." The approach to claim interpretation should
not require the specification to take a back seat to the dictionary
in defining claim terminology. Rather, the specification should
govern the use of dictionary definitions as necessary. Phillips v.

6 AWH Corp., 415 F.3d at 1320-1321, 75 USPQ2d at 1332, cautioned:

11 Assigning . . . a limited role to the specification, and
in particular requiring that any definition of claim language
in the specification be express, is inconsistent with our
rulings that the specification is "the single best guide to
the meaning of a disputed term," and that the specification
"acts as a dictionary when it expressly defines terms used in
the claims or when it defines terms by implication."
Vitronics, 90 F.3d at 1582

16 In this case, the Examiner's Answer first cites and relies
upon a dictionary to define the term "vaccine" appearing in
appellant's Claims 189-191 and then allows that definition not only
to support, but to set the foundation for, the examiner's strongest
case for unpatentability thereof under 35 U.S.C. § 112, first
21 paragraph. In so doing, the examiner erred.

Accordingly, we might decline to review the appealed
rejections of Claims 189-191 under 35 U.S.C. § 112, first
paragraph, and remand the case to the examiner because the examiner
interpreted the terms of the claims on appeal, and thus the full
26 scope and content of the claimed subject matter, based primarily on

1 a dictionary definition of the term "vaccine," seemingly without
considering the express language of the claims or significant
teachings in the supporting specification. In deciding issues
arising under 35 U.S.C. § 112, first paragraph, the specification
as a whole must be considered. In re Wright, 866 F.2d 422, 424,
6 9 USPQ2d 1649, 1651 (Fed. Cir. 1989). Prior to considering whether
the invention claimed is adequately described in, or the claimed
invention would have been enabled by, appellant's specification as
a whole, the full scope and content of the invention claimed must
be determined in light of the specification's teaching. Id.
11 Issues involving the patentability of claimed subject matter under
35 U.S.C. § 112, first paragraph (adequate written description
and/or enablement), and under 35 U.S.C. § 102/103 (anticipation or
obviousness) cannot, and properly should not, be considered until
the full scope and content of the claimed subject matter has been
16 determined. In re Moore, 439 F.2d 1232, 169 USPQ 236 (CCPA 1971),
instructs at 1235, 169 USPQ at 238, "[T]he claims must be analyzed
first in order to determine exactly what subject matter they
encompass." Accord In re Angstadt, 537 F.2d 498, 501, 190 USPQ
214, 217 (CCPA 1976). "Before considering the rejections under
21 35 U.S.C. §§ 103 and 112, we must first decide . . . [what] the
claims include within their scope." In re Geerdes, 491 F.2d 1260,

1 1262, 180 USPQ 789, 791 (CCPA 1974). It is improper to analyze the
claimed subject matter and consider the merits of rejections under
35 U.S.C. §§ 103 and 112 "relying on what at best are speculative
assumptions as to the meaning of the claims." In re Steele,
305 F.2d 859, 862-863, 134 USPQ 292, 295 (CCPA 1962).

6 On the other hand, the Federal Circuit has instructed that the
mode of claim interpretation used by the courts when litigating
issued patents differs from the mode used during prosecution of an
application pending in the Patent and Trademark Office. In re
Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1321-1322 (Fed. Cir.
11 1989). Zletz, 893 F.2d at 321, 13 USPQ2d at 1322, instructs that
claims of pending applications must be interpreted as broadly as
their terms reasonably allow, and there is no reason to read
limitations found in the specification into the claims.

Nevertheless, Zletz instructed, id. at 321, 13 USPQ2d at 1322,

16 "When applicant states the meaning that the claim terms are
intended to have, the claims are examined with that meaning . . .
." In short, whether interpreting the scope and content of subject
matter claimed in a patent application pending in the PTO or in an
issued patent, "[c]laims must always be read in light of the
21 specification." In re Fout, 675 F.2d 297, 300, 213 USPQ 532, 535

1 (CCPA 1982). Accord Phillips v. AWH Corp., 415 F.3d at 1316,
75 USPQ2d at 1328.

Here, the examiner appears to have defined the terms, and
accordingly the scope and content, of appellant's claims solely by
reference to a dictionary definition of the term "vaccine". The
6 examiner appears to have disregarded inconsistent instruction in
appellant's specification. Thus, as interpreted by the examiner of
the application on appeal, appellant's composition Claims 186-191
are directed to "vaccines" as defined by a dictionary, irrespective
of the claim language or the specification's teachings. In so
11 doing, the examiner erred. Nevertheless, due to the length of
prosecution in this case, we shall not remand this case to the
examiner for remedial claim interpretation.

Appellant's composition Claims 189-191 are drawn to a
composition encompassed by Claim 186 "in the form of a vaccine".

16 Claims 186-188 are all directed to compositions comprising an
isolated tumor rejection antigen precursor (TRAP) protein
encompassed by Claim 183 and a pharmaceutically appropriate
ingredient. Thus, appellant claims compositions in the form
of a vaccine comprising an isolated TRAP protein and a
21 pharmaceutically appropriate ingredient. For further definition of
the claim terminology, we look to appellant's specification.

1 We find the following passages reproduced from appellant's
specification most significant to the task of claim interpretation
before us. The specification teaches:

6 A class of antigens has been recognized which are
presented on the surface of tumor cells and are recognized by
cytotoxic T cells, leading to lysis. This class of antigens
will be referred to as "tumor rejection antigens" or "TRAs"
hereafter. TRAs may or may not elicit antibody responses.
The extent to which these antigens have been studied, has been
via cytolytic T cell characterization studies, in vitro i.e.,
11 the study of the identification of the antigen by a particular
cytolytic T cell ("CTL" hereafter) subset. The subset
proliferates upon recognition of the presented tumor rejection
antigen, and the cells presenting the antigen are lysed.
16 Characterization studies have identified CTL clones which
specifically lyse cells expressing the antigens. . . .

(See col. 2, l. 31-43, of U.S. Patent 5,925,729 ('729), which
issued July 20, 1999, from Application 08/142,368, filed May 2,
1994, from which the present application was divided.);

21 The gene [which codes for the tumor rejection antigen
precursors which are processed to form the presentation tumor
rejection antigens] is useful as a source for the isolated and
purified tumor rejection antigen precursor and the TRAs
themselves, either of which can be used as an agent for
26 treating the cancer for which the antigen is a "marker", as
well as in various diagnostic and surveillance approaches to
oncology The tumor rejection antigen precursor may be
expressed in cells transfected by the gene, and then used to
generate an immune response against a tumor of interest.

31 ('729, col. 3, l. 25-38);

EXAMPLE 13

36 . . . This peptide when administered to samples of P0.HTR
cells in the presence of CTL cell lines specific to cells

1 presenting it, led to lysis of the P0.HTR cells, lending
support to the view that peptides based on the product
expressed by the gene can be used as vaccines.

6 ('729, col. 12, l. 31-36);

EXAMPLE 34

11 The usefulness of the TRAPs, as well as TRAs derived
therefrom, was exemplified by the following.

Exon 3 of mage 1 was shown to transfer expression of
antigen E. As a result, it was decided to test whether
synthetic peptides derived from this exon 3 could be used to
confer sensitivity to anti-E CTL.

16 To do this, and using standard protocols, cells normally
insensitive to anti-E/CTLs were incubated with the synthetic
peptides derived from Exon 3.1. Using the CTL lytic assays
described supra on P815A, and a peptide concentration of 3 mM,
21 the peptide Glu-Ala-Asp-Pro-Thr-Gly-His-Ser-Tyr was shown to
be the best. The assay showed lysis of 30%, indicating
conferring of sensitivity to the anti-E CTL.

26 ('729, col. 22, l. 34-47);

31 As the foregoing discussion makes clear, the sequences
code for "tumor rejection antigen precursors" ("TRAPs") which,
in turn, are processed into tumor rejection antigens ("TRAs").
Isolated forms of both of these categories are described
herein, including specific examples of each. Perhaps the
most noteworthy aspect is as vaccines for treating various
cancerous conditions. The evidence points to presentation of
TRAs on tumor cells, followed by the development of an immune
response and deletion of the cells. The examples show that
36 when various TRAs are administered to cells, a CTL response is
mounted and presenting cells are deleted. This is behavior
characteristic of vaccines, and hence TRAPs, which are
processed into TRAs, and the TRAs themselves may be used,
either alone or in pharmaceutically appropriate compositions,
41 as vaccines. Similarly, presenting cells may be used in the
same manner, either alone or as combined with ingredients to
yield pharmaceutical compositions. Additional materials which

1 may be used as vaccines include isolated cells which present
the TRA molecule on their surface, as well as TRAP fragments,
mutated viruses, especially etiolated forms, and transfected
6 bacteria. "Fragments" as used herein refers to peptides which
are smaller than the TRA, but which possess the properties
required of a vaccine, as discussed supra. Another vaccine
comprises or consists of complexes of TRA and HLA molecule.
Vaccines of this type described herein may be used
preventively, i.e., via administration to a subject in an
amount sufficient to prevent onset of a cancerous condition.

11 The generation of an immune response, be it T-cell or
B-cell related, is characteristic of the effect of the
presented tumor rejection antigen. With respect to the Bcell
response, this involves, inter alia, the generation of
16 antibodies to the TRA, i.e., which specifically bind thereto.
In addition, the TRAP molecules are of sufficient size to
render them immunogenic, and antibodies which specifically
bind thereto are a part of this invention. . . .

21 ('729, col. 24, l. 25-61); and

There are therapeutic aspects of this invention as well.
The efficacy of administration of effective amounts of TRAPs
and TRAs as vaccines has already been discussed supra.
26 Similarly, one may develop the specific CTLs in vitro and
then administer these to the subject. Antibodies may be
administered, either polyclonal or monoclonal, which
specifically bind to cells presenting the TRA of interest.
. . . Thus, "targeted" antibody therapy is included herein,
31 as is the application of deletion of the cancerous cells by
the use of CTLs.

('729, col. 26, l. 13-25).

36 Based solely on the claim language and all of the
aforementioned teachings in the appellant's specification, we
conclude that the compositions of appellant's Claims 186-191 are
not limited to dictionary-defined vaccines. Compositions claimed

1 "in the form of a vaccine" may be vaccines even though they are not
dictionary-defined vaccines. The critical question is whether or
not the term "vaccine" in the specification is therein defined in
accordance with the examiner's strict interpretation of the term
vaccine or not.

6 Citing page 309 of the Illustrated Dictionary of Immunology to
conventionally define the term "vaccine" in appellant's claims, the
examiner requires appellant's specification to establish that the
full scope of the claimed compositions stimulate not only a
specific immune response, be it antibody or T-cell related, but an
11 immune response sufficiently strong to neutralize all pathogens in
an afflicted subject or induce active immunity in a nonimmune
subject. Relying on information disclosed in publications of
record to back its unpatentability arguments, the examiner stated
that the art shows that "known MAGE molecules exhibit extremely low
16 immunogenicity and initiation of a strong immune response to tumor
antigens is [sic, in] vivo is an extremely rare event" (EA 13,
sixth para.). More specifically, the examiner argues (EA 14,
fourth para.):

21 Kirkin et al. (APMIS 106: 665-679, 1998) reviews
melanoma-associated antigens recognized by cytotoxic T
lymphocytes and notes their genuinely low immunogenicity
(see entire document, including Abstract on page 665 and
Immunogenicity of tumor cells on pages 673-674). For example,

1 "from an immunological point of view, the MAGE antigens
represent very good targets for immunotherapy" and yet "so far
only one patient has shown an immune response to this group of
antigens, suggesting an extremely low immunogenicity of the
MAGE antigens" (see page 669, column 2, paragraph 1).

6 Next, publications are cited to show that persons skilled in
the art had not been able to show any correlation between structure
throughout the MAGE family of antigens and the requisite function,
i.e., a strong immune response. More specifically, the examiner
11 argues (EA 13, last para., through EA14, third para.):

In discussing the structure and expression of MAGE family
genes, De Plaen et al. (Immunogenetics 40: 360-369, 1994)
note: "Throughout the MAGE family . . . , there is considerable
conservation of hydrophylic and hydrophobic regions,
16 suggesting that the proteins produced by all these genes may
exert very similar function. At the present time, however,
there is no indication regarding this function." (See
page 367, column 2, paragraph 2).

21 . . . While the MAGE genes may have the potential to code
for antigens that could be targets for specific anti-tumor T
lymphocyte responses, such responses would rely upon various
regions of the different MAGE proteins contributing peptides
that combine with various HLA class I molecules (Page 368,
26 column 1, paragraph 2).

.

31 While such efforts may provide the groundwork for
determining a MAGE tumor antigen precursor, "it is difficult
to predict whether therapeutic success will be achieve [sic],
even if a significant increase in anti-tumor cytotoxic
lymphocytes is obtained by immunization" (see Boon et al.
(Int. J. Cancer 54: 177-180, 1993; see page 178, column 2,
36 paragraph 2).

1 Relying on his strict interpretation of the scope and content
of the subject matter appellant claims, the examiner had basis for
finding that "[d]efining human tumor antigen or tumor antigen
precursors has not been readily apparent to the skilled artisan"
(EA 14-15, bridging para., first sentence). The examiner clarified
6 his position (EA 15, third full para.; emphasis added):

 Here, the specification does not provide sufficient
written description of a genus of MAGE tumor rejection antigen
precursors based upon the limited disclosure/recitation of one
11 nucleic acid encoding MAGE-1 or upon the limited information
(nucleic acids but not cDNA sequences nor amino acid sequences
nor isolation of MAGE TRAP protein) on each one of MAGE 1-11
TRAP proteins that can be isolated from melanoma cells.
There is insufficient written description of the structure/
sequences of nucleic acids or which complementary . . . [sic]
16 complementary sequence can hybridize to SEQ ID NO: 8 and
encode a genus of diverse tumor rejection antigen precursors
and, in turn, provide the appropriate structural and
functional attributes of a genus of tumor antigen precursors,
with distinct structural, expression and functional
21 properties.

 The problem with the examiner's argument is that the
functional attributes and properties by which the examiner defines
and characterizes the scope and content of the vaccines to which
appellant's claims are directed are inconsistent with the
26 definitions and characterizations of the claimed compositions in
appellant's supporting specification. The examiner defines and
characterizes the vaccines and/or compositions in the form of
vaccines much more stringently than appellant's specification

1 defines and characterizes the scope and content of the same subject matter.

For example, referring to the technical dictionary definition of vaccine the examiner concluded that the inventions appellant claims, to the extent they encompass vaccines, are directed to
6 vaccines which must induce a strong immune response in a nonimmune subject, i.e., the vaccines must stimulate an immune response sufficiently strong to neutralize pathogens in an afflicted subject or induce active immunity in a nonimmune subject. However, appellant's specification indicates that the claimed vaccines may
11 or may not involve therapeutic aspects ('729, col. 26, l. 13-25). They may or may not elicit antibody responses ('729, col. 2, l. 31-43). According to appellant's specification, it is enough that a fraction of cells presenting the TRAs are identified and lysed by CTLs ('729, col. 2, l. 13-25; '729, col. 12, l. 31-36
16 (Example 13)). All that is required of appellant's TRAP vaccines is stimulation of an immune response against a tumor of interest ('729, col. 3, l. 25-38). Example 34 teaches that lysis of 30% of insensitive cells upon which sensitivity to anti-E CTL is said to have been conferred shows anti-E CTL sensitivity indicative of an
21 immune response ('729, col. 22, l. 34-47). Appellant's specification repeatedly states that "generation of an immune

1 response, be it T-cell or B-cell related, is characteristic of the
effect of the presented tumor rejection antigen" ('729, col. 24, l.
54-56). Appellant's specification instructs that evidence of an
immune response, e.g., stimulation of a CTL response and deletion
of TRA-presenting tumor cells, is behavior characteristic of
6 vaccines, irrespective of its strength ('729, col. 24, l. 31-39).

Accordingly, we conclude that the examiner committed
reversible error in requiring appellant's specification to
establish that the compositions it claims elicit a strong immune
response and induce active immunity to pathogens in a nonimmune
11 subject. Appellant's specification teaches that evidence of an
immune response characterizes the vaccines it claims. Citing In re
Bundy, 642 F.2d 430, 209 USPQ 48 (CCPA 1981), the Federal Circuit
noted in Cross v. Iizuka, 753 F.2d 1040, 1048 n.17, 224 USPQ 739,
746 n.17 (Fed. Cir. 1985):

16 Variation in potency . . . is a matter of degree of activity,
see Bundy, 642 F.2d at 433, 209 USPQ at 51, but is still
indicative of activity. There is no requirement that the
compounds have the same degree of activity. Id., 209 USPQ
at 51.

21 In re Bundy, 642 F.2d at 433, 209 USPQ at 51, instructs:

26 There is no requirement that all [compounds claimed] have the
same degree of activity for each use. What is necessary to
satisfy the how-to-use requirement of § 112 is the disclosure
of some activity coupled with knowledge as to the use of this
activity.

1 During prosecution of a patent application in the PTO, the
examiner must read the application's claims as broadly as their
terms reasonably allow. However, the claims should not be read
unreasonably in a manner inconsistent with the specification.

B. Burden of proof

6 1. Enablement

The PTO has the initial burden to show that the full scope of
the subject matter appellant claims is not patentable under
35 U.S.C. § 112, first paragraph. In re Marzocchi, 439 F.2d 220,
169 USPQ 367 (CCPA 1971), explained at 223, 169 USPQ at 369:

11 It has never been contended that appellants . . . intended
only to . . . [claim] a single compound. Accepting, therefore
 . . . a generic one, its recitation must be taken as an
assertion by appellants that all of the "considerable number
of compounds" which are included within the generic . . .
16 [claim] would, as a class, be operative to produce the
asserted . . . characteristics. The only relevant concern of
the Patent Office under these circumstances should be over the
truth of any such assertion. The first paragraph of § 112
requires nothing more than objective enablement. How such a
21 teaching is set forth, either by use of illustrative examples
or by broad terminology, is of no importance.

 As a matter of Patent Office practice, then, a
specification disclosure which contains a teaching of the
26 manner and process of making and using the invention in terms
which correspond in scope to those used in describing and
defining the subject matter sought to be patented must be
taken as in compliance with the enabling requirement of the
first paragraph of § 112 unless there is reason to doubt the
31 objective truth of the statements contained therein which must
be relied on for enabling support.

1 Marzocchi added, 439 F.2d at 224, 169 USPQ at 370:

6 [I]t is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth of accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure.

11 The court in Marzocchi was "constrained to conclude that the record before us contains insufficient grounds for questioning the accuracy of appellants' teaching that any [of the compounds claimed] . . . will function to accomplish the asserted result."

16 Id. See also In re Brana, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995), and In re Bundy, 642 F.2d 430, 433, 209 USPQ 48, 51 (CCPA 1981).

21 Applicants need not know how or why their inventions work to satisfy the requirements of 35 U.S.C. § 112, first paragraph. The Federal Circuit noted in Cross v. Iizuka, 753 F.2d 1040, 1042 n.3, 224 USPQ 739, 741 n.3 (Fed. Cir. 1985):

26 [I]t is axiomatic that an inventor need not comprehend the scientific principles on which the practical effectiveness of his invention rests, nor is the inventor's theory or belief as to how his invention works a necessary element in the specification to satisfy the enablement requirement of 35 U.S.C. § 112. Fromson v. Advance Offset Plate, Inc., 720 F.2d 1565, 1570, 219 USPQ 1137, 1140 (Fed. Cir. 1983).

1 Newman v. Quigg, 877 F.2d 1575, 1581-1582, 11 USPQ2d 1340, 1345
(Fed. Cir. 1989), cert. denied, 495 U.S. 932 (1990), instructs:

6 While it is not a requirement of patentability that an
inventor correctly set forth, or even know, how or why the
invention works, Diamond Rubber Co. v. Consolidated Rubber
Tire Co., 220 U.S. 428, 435-36 (1911); Fromson v. Advance
Offset Plate, Inc., 720 F.2d 1565, 1570, 219 USPQ 1137, 1140
(Fed. Cir. 1983), neither is the patent applicant relieved of
the requirement of teaching how to achieve the claimed result,
even if the theory of operation is not correctly explained or
11 even understood. In re Isaacs, 347 F.2d 887, 892, 146 USPQ
193, 197 (CCPA 1965); In re Chilowsky, 229 F.2d 457, 463, 108
USPQ 321, 326 (CCPA 1956).

16 Correctly interpreting the scope and content of appellant's
claims in light of the specification; absolving the specification
of any need to explain or understand why appellant found that
MAGE TRAPS encoded by a nucleic acid molecule, the complementary
sequence of which hybridizes to SEQ ID NO: 8 at 0.1xSSC, 0.1% SDS,
induce an immune response; and recognizing the examiner's burden of
21 proof, we now consider the argument that appellant's specification
does not show any correlation between structure throughout the MAGE
family of antigens and their capacity to induce an immune response.
We revisit the evidence in support of this argument (EA 13, last
para., through EA14, third para.):

26 In discussing the structure and expression of MAGE family
genes, De Plaen et al. (Immunogenetics 40: 360-369, 1994)
note: "Throughout the MAGE family . . ., there is considerable
conservation of hydrophylic and hydrophobic regions,
suggesting that the proteins produced by all these genes may

1 The references cited by the examiner are said to acknowledge
that there is considerable conservation of hydrophylic and
hydrophobic regions of the MAGE family of genes, suggesting that
the proteins produced by all these genes may exert a very similar
function. Nevertheless, De Plaen et al., Immunogenetics, Vol. 40:
6 360-369 (1994), is cited for its recognition at page 367, col. 2,
para. 2, that this very similar function was unknown in 1994.
However, in this case we must consider the knowledge and skill in
the art as of the March 17, 1997, filing date of Application
08/819,669, to decide the merits of the examiner's rejections under
11 35 U.S.C. § 112, first paragraph. Moreover, while the examiner
relies upon the same article for the inference that "MAGE genes may
have the potential to code for antigens that could be targets for
specific anti-tumor T lymphocyte responses," the examiner suggests
that responses to different HLA class I molecules may rely upon
16 different regions of the different MAGE proteins. The examiner's
suggestion, or course, is entitled to no more weight than whatever
speculation presented to the contrary.

 Ultimately, the examiner relies upon the 1993 Boon publication
to support his position that therapeutic success using the full
21 scope of MAGE TRAPs encompassed by appellant's claims would have
remained difficult to predict in 1997 "even if a significant

1 increase in anti-tumor cytotoxic lymphocytes is obtained by
immunization" in 1993. The examiner cites column 2, paragraph 2,
of Boon, Int. J. Cancer, Vol 54, pages 177-180, 178 (1993), for the
following statement:

6 While these are exciting prospects, it is difficult to
predict whether therapeutic success will be achieved, even if
a significant increase in anti-tumor CTL is obtained by
immunization. Variants having lost the expression of MAGE-1
may arise and allow the tumor to escape the immune response.
11 Loss of HLA expression has been documented in many tumors and
will render them refractory to this therapy It is
hoped that some of the losses in HLA expression will be
reversible

On the other hand, the same 1993 Boon publication states that an
16 immune response is predictable. "Successful immunization should
generate a significant increase in these precursors" (Boon 1993,
p. 178, col. 2, first full para.). Ultimately, Boon 1993 teaches
(Boon 1993, p. 178, col. 2, final para.):

21 Prospects will undoubtedly improve if we can attack
tumors through several antigens. This should improve the
efficiency of the attack against antigenic cells and decrease
the probability of resistance due to antigen-loss variants.
On this count, we are optimistic. The methods that have led
to the identification of a first human gene coding for tumor-
26 rejection antigens should lead soon to the identification of
others. This should also considerably expand the cancer
patient population that could benefit from specific
immunotherapy.

31 In short, the examiner's arguments that appellant's
specification inadequately describes, and would not have enabled

1 persons skilled in the art to make and use, the full scope of the
subject matter claimed are weakly based in fact and law.

Appellant's specification teaches, and supports its teaching with
examples, that the isolated MAGE TRAP proteins claimed are

characterized by their source melanoma cells, their ability to

6 induce an immune response in a nonimmune subject, and sequences

which are complementary to the nucleic acid molecules which encode
them and will hybridize to SEQ ID NO: 8 at 0.1xSSC, 0.1% SDS. The

characterization of the isolated MAGE TRAP proteins claimed in

appellant's specification is presumed valid absent evidence which

11 undermines the credibility of the characterization in appellant's

specification. The examiner does not criticize the limitation as

to source. Nor does the examiner deny that all MAGE TRAPs claimed

whose MAGE TRAs have been shown to induce an immune response are in

fact encoded by nucleic acid molecules whose complements will

16 hybridize to SEQ ID NO: 8 under the stringent conditions specified

in the claims. The examiner's case for both inadequate description

and nonenablement appears to stand or fall with the facts that:

(1) the specification does not establish that there is a 100%

correlation between the ability of polynucleotide sequences which

21 are complementary to polynucleotide sequences which encode MAGE

TRAPs to hybridize to SEQ ID NO: 8 and induction of an immune

1 response by their corresponding MAGE TRAs; (2) evidence in the
specification shows that not all polynucleotide sequences which
hybridize to SEQ ID NO: 8 are complementary to a polynucleotide
sequence which encodes a MAGE TRAP protein whose corresponding MAGE
TRAs induce an immune response, and (3) little or no evidence
6 relative to MAGE TRAPs new to the specification supporting the
claims of Application 08/819,669 here on appeal has been provided
because of cloning difficulties.

Again, the statements made in the specification supporting the
claims before us are presumed correct. In re Marzocchi, supra.

11 The examiner has the burden to show otherwise. Here, contrary to
the examiner's finding, we find that appellant's specification does
establish that there is a correlation between hybridization to SEQ
ID NO: 8, polynucleotides which encode MAGE TRAP proteins, and the
capacity for the corresponding MAGE TRAs to induce an immune
16 response. That there is evidence in appellant's specification that
some experimentation may be required to reduce the full scope of
the claimed invention to practice is more indicative of a higher
level of guidance and instruction designed to describe and enable
one skilled in the art to make and use the full scope of the
21 invention claimed. In re Angstadt, 537 F.2d at 504, 190 USPQ
at 219, instructs:

1 [T]he PTO has the burden of giving reasons, supported by the
record as a whole, why the specification is not enabling.
In re Armbruster, 512 F.2d 676, 185 USPQ 152 (CCPA 1975).
Showing that the disclosure entails undue experimentation
is part of the PTO's initial burden under Armbruster: this
6 court has never held that evidence of the necessity for any
experimentation, however slight, is sufficient to require the
applicant to prove that the type and amount of experimentation
needed is not undue.

11 . . . Depriving inventors of claims which adequately
protect them and limiting them to claims which practically
invite appropriation of the invention while avoiding
infringement inevitably has the effect of suppressing
disclosure. What the dissent seems to be obsessed with is the
16 thought of catalysts which won't work to produce the intended
result. Appellants have enabled those in the art to see that
this is a real possibility, which is commendable frankness in
a disclosure. Without undue experimentation or effort or
expense the combinations which do not work will readily be
21 discovered and, of course, nobody will use them and the claims
do not cover them. . . . [T]o make everything predictable in
advance . . . is impracticable and unreasonable.

We conclude that the examiner has not met his initial burden
26 to prima facie establish the appellant's specification would not
have enabled the full scope and content of Claims 183-191 of
Application 08/819,669, as of its March 17, 1997, filing date.
Accordingly, the appealed final rejections of Claims 183-191 under
35 U.S.C. § 112, first paragraph, for nonenablement are reversed.

31 2. Description requirement

The examiner relies on substantially the same evidence and
arguments in support of his rejections of Claims 183-191 of
Application 08/819,669, filed March 17, 1997, under 35 U.S.C.

1 § 112, first paragraph, as based on a specification providing an
inadequate written description of the subject matter claimed, that
he relied upon in support of his rejections for nonenablement.
In so doing, it appears that the examiner overlooked our reviewing
court's warning in Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563,
6 19 USPQ2d 1111, 1117 (Fed. Cir. 1991):

11 [W]e hereby reaffirm, that 35 USC 112, first paragraph,
requires a "written description of the invention" which is
separate and distinct from the enablement requirement. The
purpose of the "written description" requirement is broader
than to merely explain how to "make and use"; the applicant
must also convey with reasonable clarity to those skilled in
the art that, as of the filing date sought, he or she was in
possession of the invention.

16 At the very least, compliance with the enablement requirement of
35 U.S.C. § 112, first paragraph, is a question of law. In re
Vaeck, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991).
Compliance with its written description requirement is a question
of fact. Vas-Cath, Inc. v. Mahurkar, 935 F.2d at 1563, 19 USPQ2d
21 at 1116.

26 The examiner acknowledges Vas-Cath's warning (EA 12, fourth
full para.). However, the examiner appears to have misunderstood
the court's statement that the specification conveys to persons
skilled in the art that the inventor was in possession of the
invention claimed when the skilled artisan recognized that the

1 inventor invented the subject matter claimed (EA 12, fourth full
para.). See In re Gosteli, 872 F.2d 1008, 1002, 10 USPQ2d 1614,
1618 (Fed. Cir. 1989). Regarding the last sentence of Vas-Cath's
warning, Enzo Biochem. Inc. v. Gen-Probe Inc., 323 F.3d 956,
63 USPQ2d 1609 (Fed. Cir. 2002), clarified at 969, 63 USPQ2d 1617:

6 That portion of the opinion in Vas-Cath, however, merely
states a purpose of the written description requirement,
viz., to ensure that the applicant had possession of the
11 invention as of the desired filing date. It does not state
that possession alone is always sufficient to meet that
requirement. Furthermore, in Lockwood v. American Airlines,
Inc., we rejected Lockwood's argument that "all that is
necessary to satisfy the description requirement is to show
that one is 'in possession' of the invention." 107 F.3d
1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Rather,
16 we clarified that the written description requirement is
satisfied by the patentee's disclosure of "such descriptive
means as words, structures, figures, diagrams, formulas,
etc., that fully set forth the claimed invention." Id.

21 . . . Application of the written description . . . is
not subsumed by the "possession" inquiry. A showing of
"possession" is ancillary to the statutory mandate that
"[t]he specification shall contain a written description of
the invention," and that requirement is not met if, despite a
26 showing of possession, the specification does not adequately
describe the claimed invention. After all . . . one can
show possession of an invention by means of an affidavit or
declaration during prosecution, as one does in an interference
or when one files an affidavit under 37 C.F.R. § 1.131 to
31 antedate a reference. However, such a showing of possession
alone does not cure the lack of a written description in the
specification, as required by statute.

Perhaps the purpose of the written description requirement is best
36 stated in Reiffin v. Microsoft Corp., 214 F.3d 1342, 1345-46,

1 54 USPQ2d 1915, 1917 (Fed. Cir. 2000), as follows:

The purpose of this provision is to ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification.

6 The adequacy or inadequacy of the written description of the invention claimed varies with the facts in each case. As said in Capon v. Eshhar, 418 F.3d 1349, 1357-1358, 76 USPQ2d 1078, 1084-1085 (Fed. Cir. 2005):

11 The descriptive text needed to meet these requirements varies with the nature and scope of the invention at issue, and with the scientific and technical knowledge already in existence. The law must be applied to each invention that enters the patent process, for each patented advance is novel
16 in relationship to the state of the science. Since the law is applied to each invention in view of the state of relevant knowledge, its application will vary with differences in the state of knowledge in the field and differences in the predictability of the science.

21 . . . In Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1332 [65 USPQ2d 1385] (Fed. Cir. 2003) the court explained further that the written description requirement may be satisfied "if in the knowledge of the art the disclosed
26 function is sufficiently correlated to a particular, known structure."

31 The "written description" requirement must be applied in the context of the particular invention and the state of the knowledge.

36 The "written description" requirement states that the patentee must describe the invention; it does not state that every invention must be described in the same way. As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution.

1 We found previously herein that the teachings in appellant's
specification as a whole, including the representative examples and
sequences reported, reasonably would have led persons skilled in
the art to believe that there is a correlation between the ability
of a complement to a polynucleotide sequence which encodes a MAGE
6 TRA able to induce an immune response in a nonimmunized subject
derived from a claimed precursor and the complement's ability to
hybridize to SEQ ID NO: 8. The result is not one hundred percent
predictable. Nevertheless, we find that the teachings in
appellant's specification would have led persons skilled in the
11 art reasonably to expect success using MAGE TRAPs encoded by
polynucleotide sequences complementary to polynucleotide sequences
which hybridize to SEQ ID NO: 8 to induce an immune response of
some kind in a nonimmunized subject. In Capon v. Eshhar, 418 F.3d
at 1358-1359, 76 USPQ2d at 1085, the court said (emphasis added):

16 It is well recognized that in the "unpredictable" fields
of science, it is appropriate to recognize the variability in
the science in determining the scope of the coverage to which
the inventor is entitled. Such a decision usually focuses on
the exemplification in the specification

21 Precedent illustrates that the determination of what is
needed to support generic claims to biological subject matter
depends on a variety of factors, such as the existing
knowledge in the particular field, the extent and content
26 of the prior art, the maturity of the science or technology,
the predictability of the aspect at issue, and other
considerations appropriate to the subject matter.

1 It is not necessary that every permutation within a
generally operable invention be effective in order for an
inventor to obtain a generic claim, provided that the effect
is sufficiently demonstrated to characterize a generic
6 invention. See *In re Angstadt*, 537 F.2d 498, 504 [190 USPQ
214] (CCPA 1976) ("The examples, both operative and inoperative,
are the best guidance this art permits, as far as we can
conclude from the record").

Here, we also have significant "other considerations
11 appropriate to the subject matter." Capon v. Eshhar, 418 F.3d
at 1358, 76 USPQ2d at 1085. In this case, appellant directed the
examiner's attention to Example 9 of the USPTO's Guidelines for
Examination of Patent Applications under the 35 U.S.C. § 112, first
paragraph, "Written Description" Requirement, 66 Fed. Reg. 1099
16 (Jan. 5, 2001) ("Guidelines") (Reply Brief, p. 8 and attachment 1
thereto (RB 8 and att. 1)).

Example 9 of the Guidelines deals with a claim to "[a]n
isolated nucleic acid that specifically hybridizes under highly
stringent conditions to the complement of the sequence set forth in
21 SEQ ID NO: 1" and that encodes a protein having a specified
function (RB att 1). The analysis of the example suggests that the
claim should be found to have adequate written description because,
among other considerations, "highly stringent hybridization
conditions . . . yield structurally similar DNAs" (RB att. 1,

1 pp. 36-37, bridging para.). This reasoning was cited with approval
in Enzo Biochem. Inc. v. Gen-Probe Inc., 323 F.3d at 967, 63 USPQ2d
at 1615:

6 The PTO has . . . provided a[n] . . . example of genus
claims to nucleic acids based on their hybridization
properties, and has determined that such claims may be
adequately described if they hybridize under highly
stringent conditions to known sequences because such
conditions dictate that all species within the genus
will be structurally similar.

11 The examiner distinguished Example 9 of the Guidelines because
the "claimed genus in the instant application still encompasses an
enormous number of species with potentially widely diverse
properties and describes them structurally simply by hybridization
16 language" (Supplemental Examiner's Answer In Response To Order
Returning Undocketed Appeal To Examiner, p. 16, fifth para.). In
our view, the examiner has not adequately explained why a different
result is warranted here. That is, the examiner has not adequately
explained why the hybridization conditions recited in the claim in
21 Example 9 would show structural similarity and therefore
possession, but the hybridization conditions recited in the present
claims would not.

26 Furthermore, appellant's specification identifies an amino
acid sequence of MAGE TRAPs encompassed by Claims 183-191, and
Claims 184, 187, and 190 are limited to MAGE TRAPs comprising that

1 sequence. The examiner's analysis makes no distinction between the
patentability of appellant's claims further defined by amino acid
SEQ ID NO: 26 and not. Accordingly, we are forced to conclude that
the examiner in this case did not completely analyze the nature and
scope of the invention claimed relative to the scientific and
6 technological knowledge in existence at the pertinent time, and
accordingly, did not fully consider all evidence material to the
patentability of the subject matter defined by appellant's claims.

The court in Capon v. Eshhar, 418 F.3d at 1358, 76 USPQ2d
at 1085, instructed:

11 See In re Wallach, 378 F.3d 1330, 1333-34 [71 USPQ2d
1939] (Fed. Cir. 2004) (an amino acid sequence supports "the
entire genus of DNA sequences" that can encode the amino
acid sequence because "the state of the art has developed"
16 such that it is a routine matter to convert one to the
other)

Here, the examiner did not consider the extent to which, or the
difficulty with which, persons skilled in the art could have
identified polynucleotide sequences of the full scope of MAGE TRAPS
21 appellant claims in light of the disclosure of an amino acid
sequence of MAGE TRAPS encompassed thereby and polynucleotide SEQ
ID NO: 8 to which the complement of the polynucleotide sequences
which encode all MAGE TRAPS encompassed by appellant's claims must
hybridize under stringent conditions.

1 The examiner's verbiage in this case cannot serve to replace
the comprehensive analysis of the claimed subject matter, the
teaching in appellant's specification, the state of the art, and
the knowledge and skill of persons skilled in the art at the time
this application was filed which is required to satisfy the PTO's
6 burden to establish the unpatentability of the full scope of the
claimed subject matter under 35 U.S.C. § 112, first paragraph.
Accordingly, we must reverse all the examiner's final rejections
here on appeal.

 Nevertheless, we are not satisfied that a patent including the
11 claims here on appeal should be granted based on the record
presently before us. There are significant patentability issues
which appear not to have been raised or even considered by the
examiner.

C. Other issues

16 First, in the array of papers before us, including the appeal
brief, examiner's answer, reply brief, two supplemental examiner's
answers, and replies to the supplemental examiner's answers and art
newly submitted in support thereof, there is a running debate
between appellant and the examiner regarding the prior art status
21 of one or more recently published references relied upon by either

1 appellant or the examiner in support of their respective positions
regarding the patentability of the claims before us. The examiner
sometimes denies a reference's prior art status. Other times, the
examiner relies on a reference's prior art status. Appellant
invariably takes the opposing position.

6 We have reviewed all the art cited by appellant for its
evidentiary value in support of the respective positions of
appellant and the examiner on the critical issues before us.
Post-filing publications are not necessarily worthless and cannot
be disregarded as a matter of law. Citing In re Hogan, 559 F.2d
11 595, 605, 194 USPQ 527, 537 (CCPA 1977), the court in Plant Genetic
Systems, N.V. v. DeKalb Genetics Corp., 315 F.3d 1335, 65 USPQ 1452
(Fed. Cir. 2003), restated at 1344, 65 USPQ2d at 1459:

16 This court has approved use of later publications as evidence
of the state of the art existing on the filing date of an
application. That approval does not extend, however, to the
use of a later . . . publication disclosing a later (1962)
existing state of the art in testing an earlier (1953)
application for compliance with § 112, first paragraph. The
21 difference may be described as that between the permissible
application of later knowledge about art-related facts
existing on the filing date and the impermissible application
of later knowledge about later art-related facts . . . which
did not exist on the filing date.

26 We have considered all later knowledge of record about
art-related facts existing on the filing date of appellant's

1 application and tried to discard all later knowledge about later
art-related facts which did not exist on the filing date of
appellant's application. We find little or no evidence which
effectively undermines the presumption that appellant's
specification is a fair presentation of the state of the art and
6 the knowledge and skill of persons skilled in the art at the time
appellant's application was filed. Nor do we find evidence
sufficient to show that the examiner has satisfied his burden to
establish that appellant's specification would not have adequately
described, and/or enabled persons skilled in the art to make and
11 use, the full scope of the invention now claimed, at the time
appellant's present application was filed. Moreover, the evidence
as a whole appears to support our findings and conclusions herein
above.

Second, when the prior art status of a material publication,
16 the publication date of which predates the latest application's
filing date but postdates the filing date of an earlier filed
application for which benefit is later claimed under 35 U.S.C.
§ 119 or § 120, is debated, the examiner is generally charged with
a duty to determine whether the full scope of the subject matter

1 the applicant claims is entitled to benefit under 35 U.S.C.
§ 119 or § 120 of the earlier application's filing date. That
determination is particularly significant where, as here, the
claims of the latest application are supported by a specification
which admittedly contains new matter. To determine whether the
6 full scope of applicant's latest claims is entitled to benefit of
an earlier-filed application's filing date, and thus to determine
the prior art status of art of record published only before the
filing date of the latest application, the examiner must determine
whether the specification of the earlier-filed application would
11 have adequately described and enabled one skilled in the art to
make and use the full scope of the subject matter later claimed.
If, as may or may not be the case here, the earlier filed
specifications do not satisfy 35 U.S.C. § 112, first paragraph, for
the full scope of the subject matter claimed in the latest filed
16 application, then any intervening reference published more than one
year prior to the effective filing date of the latest application
may be prior art under 35 U.S.C. § 102(b). See In re Gosteli,
872 F.2d 1008, 1009-1010, 10 USPQ2d 1614, 1616-18 (Fed. Cir. 1989),
and In re Scheiber, 587 F.2d 59, 61-62, 199 USPQ 782, 784-85 (CCPA
21 1978). In this case, the examiner has not determined whether

1 appellant has perfected its claims for benefit of the filing dates
of its earlier-filed applications for the full scope of the subject
matter now claimed and antedated all publications disclosing MAGE-1
which were published more than one year prior to the May 2, 1994,
filing date of appellant's parent Application 08/142,368. The
6 examiner has not done so because he has not considered whether the
specification of grandparent Application 07/807,043, filed
December 12, 1991, satisfies all the requirements of 35 U.S.C.
§ 112, first paragraph, for the full scope of subject matter
encompassed by each claim here on appeal as of its December 12,
11 1991, filing date.

 The examiner in this case considered whether the full scope of
the subject matter encompassed by the claims now on appeal would
have been adequately described in, and enabled by, appellant's
parent Application 08/142,368 filed May 2, 1994. However, the
16 examiner appears not to have considered whether the full scope of
the subject matter encompassed by the claims now on appeal would
have been adequately described in, and enabled by, appellant's
grandparent Application 07/807,043, filed December 12, 1991. The
claims for benefit under 35 U.S.C. § 120 in this case are important
21 to the patentability of the subject matter defined by the claims on

1 appeal because human gene MAGE-1, which is said to encode for a
MAGE tumor rejection antigen and said to have been expressed by
some tumors, is disclosed in intervening references such as
Brasseur et al., Int. J. Cancer (Letter to the Editor), Vol. 52,
pp. 839-841 (1992), and Boon et al., Int. J. Cancer, Vol. 54,
6 pp. 177-180 (1993). In short, we recommend that the examiner
determine whether appellant has perfected its claims for benefit
under 35 U.S.C. § 120 and antedated intervening art. The examiner
has not determined the full scope and content of prior art
applicable to the claimed subject matter here on appeal.

11 Finally, we presume that the specification of Boon et al.,
U.S. Patent 5,342,774, which issued August 30, 1994, from
grandparent Application 07/807,043, filed December 12, 1991,
satisfies all requirements of 35 U.S.C. § 112, first paragraph, for
the full scope of the subject matter defined by Claim 4 thereof.

16 Claim 4 of U.S. Patent 5,342,774 reads (emphasis added):

4. An isolated nucleic acid molecule which hybridizes to the
nucleic acid molecule which codes for MAGE-1 tumor rejection
antigen precursor as set forth in SEQ ID NO: 8 under stringent
conditions and which codes for a tumor rejection precursor.

21 Our decision reversing all the appealed final rejections of
Claims 183-191 under 35 U.S.C. § 112, first paragraph, appears to
be consistent with the presumption that Claim 4 of grandparent

Appeal No. 2006-0956
Application No. 08/819,669

1 Application 07/807,043, filed December 12, 1991, now U.S. Patent
5,342,774, is directed to patentable subject matter.

Conclusion

6 Having considered all the evidence and arguments before us,
and given appropriate weight thereto, we reverse all the examiner's
final rejections of Claims 183-191 of Application 08/819,669 under
35 U.S.C. § 112, first paragraph, and remand this case for further
action consistent with the findings, conclusions, and views
expressed herein.

REVERSED; REMANDED

11



TEDDY S. GRON
Administrative Patent Judge

16



SALLY G. LANE
Administrative Patent Judge

21



ERIC GRIMES
Administrative Patent Judge

26

)
)
)
)
) BOARD OF PATENT
) APPEALS
) AND
) INTERFERENCES
)
)
)
)

Appeal No. 2006-0956
Application No. 08/819,669

- 1 Norman D. Hanson, Esq.
FULBRIGHT & JAWORSKI L.L.P.
666 Fifth Avenue
New York, NY 10103-3198
(212) 318-3000